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(54) Microdispensing opthalmic pump

(57) A microdispensing ophthalmic pump is provided for repeatedly delivering doses as small as 5 microliters within an angular operating range. The pump basically comprises a reservoir (12), a dispensing cap (18), an actuator (20) and a pump body (14) with a pump mechanism (16) disposed therein. The pump mechanism (16) is regulated by a limited-travel inlet check valve and a biased-closed outlet check valve. A failsafe mechanism is formed between the actuator (20) and dispensing cap (18) to prevent operation of the pump outside the operating range.

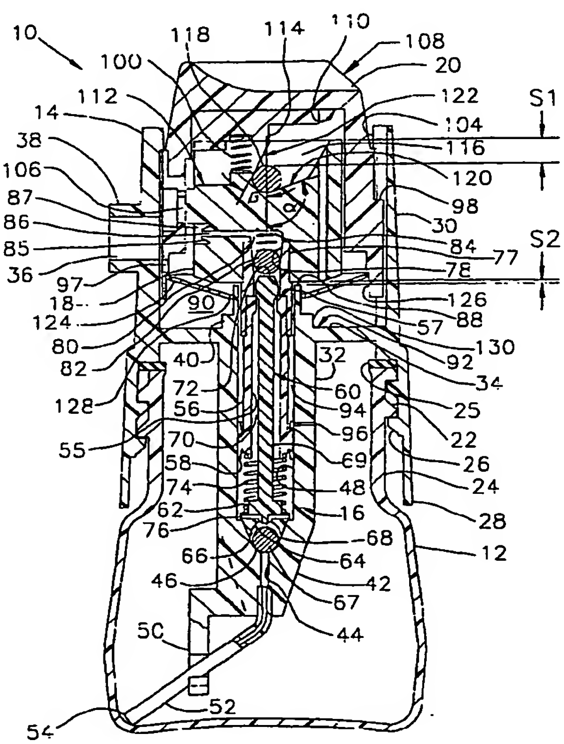

FIG. 2

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the pump if fluid disposed in the nozzle and the outlet chamber is drawn into the inner body due to the suction effect. During operation of the pump, the spring urges the outlet check valve element into a closed and seated position prior to suction being created in the inner body and ensures that a proper and full microdose of the ophthalmic fluid is maintained within the nozzle and the outlet chamber, unaffected by the suction effect.

An inlet check valve element is provided to regulate the flow of ophthalmic fluid into the pump.
Since the delivery of microdoses as small as 5 microliters involves a negligible stroke of the inlet check valve element, a protrusion is disposed opposite the inlet check valve element which restricts the check valve element's range of motion and prevents the check valve element from simply shuttling during usage. The motion of the inlet check valve element is limited so that in an open position the volume displaced by the inlet check valve element in travelling from a closed position to an open position is less than the volume of the dose being dispensed by the pump. In the preferred embodiment, this volume is the swept volume of an inlet check valve ball and is calculated by taking the product of the clearance between the inlet check valve ball and the protrusion times the cross-sectional area of the inlet check valve ball: (clearance) x [π x (radius of the ball)^2]. Although a ball is preferred, any shape inlet check valve element may be used, such as a disk, with the swept volume being determined by the product of the clearance between the inlet check valve element and the protrusion times the largest cross-sectional area of the inlet check valve element measured in a plane perpendicular to the flow of fluid through the check valve. Thus, one feature of a new and improved manually operated microdispensing pump of the subject invention is a valve arrangement sensitive to the negligible strokes associated with microdosing.

Prior to initial use, a pump of the subject invention must be primed, wherein air is expelled from the pump mechanism. The pump is primed through the repeated actuation of the pump mechanism which draws fluid therein and forces air thereout. After priming, the re-introduction of air into the pump mechanism is undesired, since air pockets may be formed within the pump mechanism which may render the pump mechanism inoperative. To prevent the entrapment of air within the pump mechanism, the pump of the subject invention can include a failsafe device, a limited volume dip tube and a spherical inlet chamber which function to prevent the introduction and entrapment of air bubbles into the pump mechanism. The failsafe device preferably comprises a ball disposed within an arcuate slotted track formed in the dispensing cap, which cooperates with an actuating block extending from the actuator. To operate the pump, the actuator is urged towards the dispensing cap with the actuating block coming into contact and pressing against the ball disposed within the track, which, under further urging, depresses the dispensing cap and activates the pump mechanism. If the pump were to be operated with the opening of the dip tube exposed to air entrapped within the reservoir, air could possibly be introduced into the pump mechanism. The slot of the failsafe device is formed to guide the ball out of alignment with the actuating block when the dip tube is positioned to be in communication with air trapped in the reservoir, with the ophthalmic fluid being within a predetermined range of fluid levels. Preferably, the slot is formed to allow the pump to operate with the nozzle discharge positioned in a range from approximately 155 to 290 degrees, going clockwise. Outside of this range, the ball will slide within the arcuate slot and prevent actuation of the pump.

To limit the entrapment of air in the pump during priming, the inlet chamber is formed to be substantially spherical to avoid the creation or entrapment of air bubbles therein. Also, during priming, as the pump is actuated with the inlet check valve element not being encompassed by ophthalmic fluid, the inlet check valve element will not provide an adequate seal against its seat and will allow fluid to freely pass the check valve element into the dip tube. This leakage, when the inlet check valve element is in a dry state, may cause an air pocket in the dip tube which prevents ophthalmic fluid from entering the pump mechanism. The air pocket will react to the actuation of the pump by rising and falling within the dip tube corresponding to the existence of suction within the pump mechanism. As a result, ophthalmic fluid is prevented from being drawn into the pump mechanism. To avoid such a problem, the dip tube of the pump of the subject invention is formed to encompass a volume less than the microdose intended to be dispensed by the pump to ensure that the inlet check valve element is submersed in ophthalmic fluid, since the inlet check valve element will not leak when encompassed by ophthalmic fluid. The dip tube has a hollow, substantially cylindric center which contains fluid from its free end to the seat of the inlet check valve element, which will be fully drawn into the pump upon a single actuation. Limiting the volume of the dip tube below the microdose of the pump ensures sufficient fluid will be drawn from the dip tube with a single actuation of the pump which will encompass the inlet check valve element and prevent the formation of an air pocket in the dip tube. Thus, another feature of a new and improved manually operated microdispensing pump of the subject invention prevents the entrapment of air within the pump mechanism.

To ensure proper operation of the pump, an annular tapered latch, formed from a resilient plastic, is provided at the base of the actuator and disposed about the inner body and pump mechanism. A corresponding annular shoulder is formed about the inner body with a top surface which comes into contact with the bottom surface of the latch with the downward translation of the actuator. The actuator can translate downward till the bottom surface of the latch is in contact with the annular shoulder without the pump dispensing any fluid. The actuator

bodiment of the new and improved pump of the subject invention.

FIG. 7 is a cross-sectional view of an alternative embodiment of the new and improved pump of the subject invention.

FIG. 8 is a plan and cross-sectional side view of the latch of the new and improved pump of the subject invention.

FIG. 9 is a plan and cross-sectional side view of the spring fingers of an alternative embodiment of the subject invention.

FIG. 10A-D are cross-sectional views of the operating range of the new and improved pump of the subject invention.

FIG. 11A-D are cross-sectional views of the jet stream dispensed by the new and improved pump of the subject invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, the first embodiment of the new and improved manually operated microdispensing pump of the subject invention is generally indicated by reference numeral 10 and is capable of delivering a microdose of ophthalmic fluid 11 to a human eye 13. Referring generally to FIGS. 1-5, the pump 10 comprises a reservoir 12, a pump body 14, a pump mechanism 16, a dispensing cap 18 and an actuator 20.

The reservoir 12 is generally cup-shaped and formed to accommodate fluid. The pump body 14 is mounted onto the reservoir 12 and secured thereto through threaded engagement of threads 22, formed on neck 24 of the reservoir 12, and threads 26, formed on a lower portion 28 of the pump body 14 which is disposed about the neck 24. An annular seal 25 is disposed between the pump body 14 and the reservoir 12 which prevents fluid from leaking through the threads 22, 26. The pump body 14 comprises a substantially cylindrical outer shell 30, a substantially cylindrical inner body 32 disposed co-axially within the outer shell 30, and a transverse bulkhead 34 joining the two cylindrical elements. The outer shell 30 is formed to define a dispensing aperture 36 with sight 38 disposed thereabout. The sight 38 allows a user of the pump 10 to aim and direct the pump's discharge.

The inner body 32 extends from both sides of the bulkhead 34 with one end 40 being open, an opposed end 42 having an inlet channel 44 and an inlet check valve seat 46 formed therein, and a cylindrical inner chamber 48 extending between the two ends 40, 42. A hook-shaped guide 50 depends from the lower end of the inner body 42 onto which dip tube 52 is mounted. The guide 50 directs the dip tube 52, which encompasses a volume less than the microdose 11, to the edge of the reservoir 12 in alignment with the sight 38. The guide 50 and the dip tube 52 allow an individual to efficiently draw fluid from the reservoir 12, since the dip tube 52 is fixed and formed to reach deep into the reservoir 12 and communicate with very low levels of fluid. Furthermore, an individual has a tendency to tilt a dispenser forward in administering a fluid; the guide 50 and an end of the dip tube 54 are aligned to consider this tendency.

A cylindrical piston 56 is slidably disposed within the inner chamber 48 with an annular seal 58 being in contact with the surface of the inner chamber 48. The piston 56 is formed with a cylindrical inner surface 55 having a constant cross-section and a top end 57 forming an opening smaller than the cross-section of the inner surface 55. A poppet 60 is located within the piston 56 and extends throughout the inner chamber 48. The poppet 60 is formed with a base 62 having a hemispherical lower surface 64, which together with the inlet check valve seat 46 form a generally spherical inlet chamber 66. The inlet channel 44 communicates with the inlet chamber 66 and together with the dip tube 52 form a passageway for fluid to pass into the pump body 14. An inlet check valve element 67, preferably a ball, is seated in the inlet check valve seat 46 within the inlet chamber 66. A protrusion 68 extends from the lower surface 64 of the poppet 60 into close proximity with the inlet check valve element 67. The protrusion 68 limits the travel of the inlet check valve element 67 within the inlet chamber 66 so that the swept volume of the inlet check valve element 67 is less than the microdose 11, calculated in a manner previously described.

A stem 69 extends from the base 62 through the piston 56 in a spatial relationship, thereby forming an annular flow path 70 therebetween. A head 72 depends from the stem 69 and has a diameter greater than the inner diameter of the piston 56. A spring 74 is disposed about the base 62 of the poppet 60, and urges the top of the piston 57 into sealing contact with the head 72. The inner chamber 48 and the annular flow path 70 receive fluid from the inlet chamber 66 through ports 76 formed in the base of the poppet 62. An outlet check valve housing 77 is mounted to the piston 56 with a tapered portion 78 being formed therein. The poppet 60 is disposed within the piston 56 by forcing the head 72 through the piston 56. The piston 56 is preferably made from low density polyethylene, which will allow the head 72, preferably made from high density polyethylene, to pass through the piston 56 without permanent deformation.

The dispensing cap 18 is mounted onto the outlet check valve housing 77. An outlet chamber 80 is formed within the dispensing cap 18 and communicates with the annular flow path 70 when the head 72 is not in contact with the piston 56. An outlet check valve element 82, preferably a ball, is located within the outlet chamber 80 and limits flow from the annular flow path 70 into the outlet chamber 80. A quick return biasing means 84 urges the outlet check valve element 82 into sealing contact with the tapered portion 78. Preferably, the quick return biasing means 84 is comprised of a conventional coil spring with a spring force of 2.9 lbs/in., as shown in FIG.

as described below is the same during priming, except the pump medium may include some air.

To dispense fluid from the pump 10, the actuator 20 is depressed into the pump body 14 with the bottom surface 128 of the latch 124 coming into contact with the annular shoulder 130, as shown in FIG. 3. The latch 124 freely deforms with further downward translation of the actuator 20. As the latch 124 continues to deform, the latch 124 generates resistance to further downward translation requiring increasing force to accomplish such translation. The force will eventually build up to a predetermined threshold force which overcomes the latch 124 and causes it to yield. As the threshold force is being reached, the actuating block 114 comes into contact with the ball 118. The threshold force necessary to overcome the latch 124 ensures the piston 56 will rapidly translate its full stroke. The resistance against downward translation can be also be regulated through the size and quantity of the air vents 97. The depression of the actuator 20 causes the air in the void 90 to compress and requires additional force for further compression and further translation. Since the air vents 97 communicate with the atmosphere and the compressed air in the void 90 is bled thereto, having minimal or none of the air vents 97 results in a slow escape for the compressed air and resistance to translation of the actuator 20. An increase in the number or size of the air vents 97 allows the compressed air to escape quicker from the void 90 and reduce the resistance against downward translation. The combination of the latch 124 and the vents 97 can be manipulated to establish a threshold force required to operate the pump 10.

As shown in FIG. 3, the actuator 20 must translate the distance S1 for the actuating block 114 to come into contact with the ball 118. As the distance S1 is translated, the latch 124 and the air vents 97 offer resistance so that a threshold force must be applied to actuate the pump 10. With the distance S1 translated, the latch 124 will be on the verge of yielding under the threshold force and the ball 118 will be in contact with the actuating block 114. The distance S2 is equal to the stroke of the piston 56, and the actuator 20 and the dispensing cap 18 can only travel the distance S2 by having the latch 124 yield and the air of the void 90 overcome. With the application of the threshold force, the latch 124 is quickly deformed with the threshold force continuously being applied thereafter, thereby causing the actuator 20, along with the dispensing cap 18 and the piston 56, to quickly travel the distance S2.

Referring to FIG. 3, as the piston 56 travels downward the distance S2, fluid within the inner chamber 48 is compressed and forced through the annular flow path 70 about the head 72, which through the downward travel of the piston 56 is separated from the top of the piston 57. The fluid rushing past the head 72 will act against the outlet check valve element 82, with the pressure of the fluid eventually overcoming the bias of the quick return biasing means 84 and causing the outlet check valve element 82 to separate from the tapered portion 78. In turn, the fluid travelling past the outlet check valve element 82 will force fluid into the discharge nozzle 86 and the microdose 11 out of the nozzle 86, which is aligned with the discharge aperture 106 and the dispensing aperture 36. Due to the threshold force required to overcome the latch 124 and the air of the void 90, the downward travel of the piston 56, through the distance S2, is rapid, resulting in a rapid surge of fluid through the nozzle 86. The microdose 11 exiting from the discharge nozzle 86 will form a non-aerosolized jet stream as shown in FIG. 11A-D. Due to the surface tension of fluid, as the microdose 11 travels away from the pump 10, it will tend to break into a series of drops with a relatively large droplet and several smaller droplets, which will all hit the eye 13 nearly simultaneously.

The yielding of the latch 124 will cause the fluid to surge past the head 72 and the outlet check valve element 82. As shown in FIG. 4, the quick return biasing means 84 will urge the outlet check valve element 82 into contact with the tapered portion 78, once the surge of fluid has bypassed the outlet check valve element 82. The piston spring 74 will urge the piston 56, the dispensing cap 18 and the actuator 20 upwards, with the biasing means 100 further urging the actuator 20 away from the dispensing cap 18. Simultaneously, the latch 124 will separate from the annular shoulder 130 and resume its undeformed, annular tapered form. The upward travel of the piston 56 increases the volume of the inner chamber 48 and creates a suction effect. As a result, the inlet check valve element 67 is drawn towards the inner chamber 48 and into contact with the protrusion 68, as depicted in FIG. 5. Fluid is then drawn from the dip tube 52 through the inlet channel 44, the inlet chamber 66 and the ports 76 into the inner chamber 48. As the inner chamber 48 fills with the drawn fluid, pressure increases therein and the inlet check valve element 67 is forced into a seated position in the seat 46.

The pump 10 can be manually actuated without the latch 124. The latch 124, however, ensures the application of the threshold force, which, in turn, ensures the application of a full dose in a jet stream, as described above.

Simultaneous to the pumping operation, the vent 96 is exposed to the annular air chamber 94 with the downward travel of the piston 56 and to ambient conditions. As such, the pressure on the surface of the fluid in the reservoir 12 is restored to atmospheric with each actuation of the pump 10.

As is readily apparent, numerous modifications and changes may readily occur to those skilled in the art, and hence it is not desired to limit the invention to the exact construction and operation shown and described, and accordingly all suitable modification equivalents may be resorted to falling within the scope of the invention as claimed.

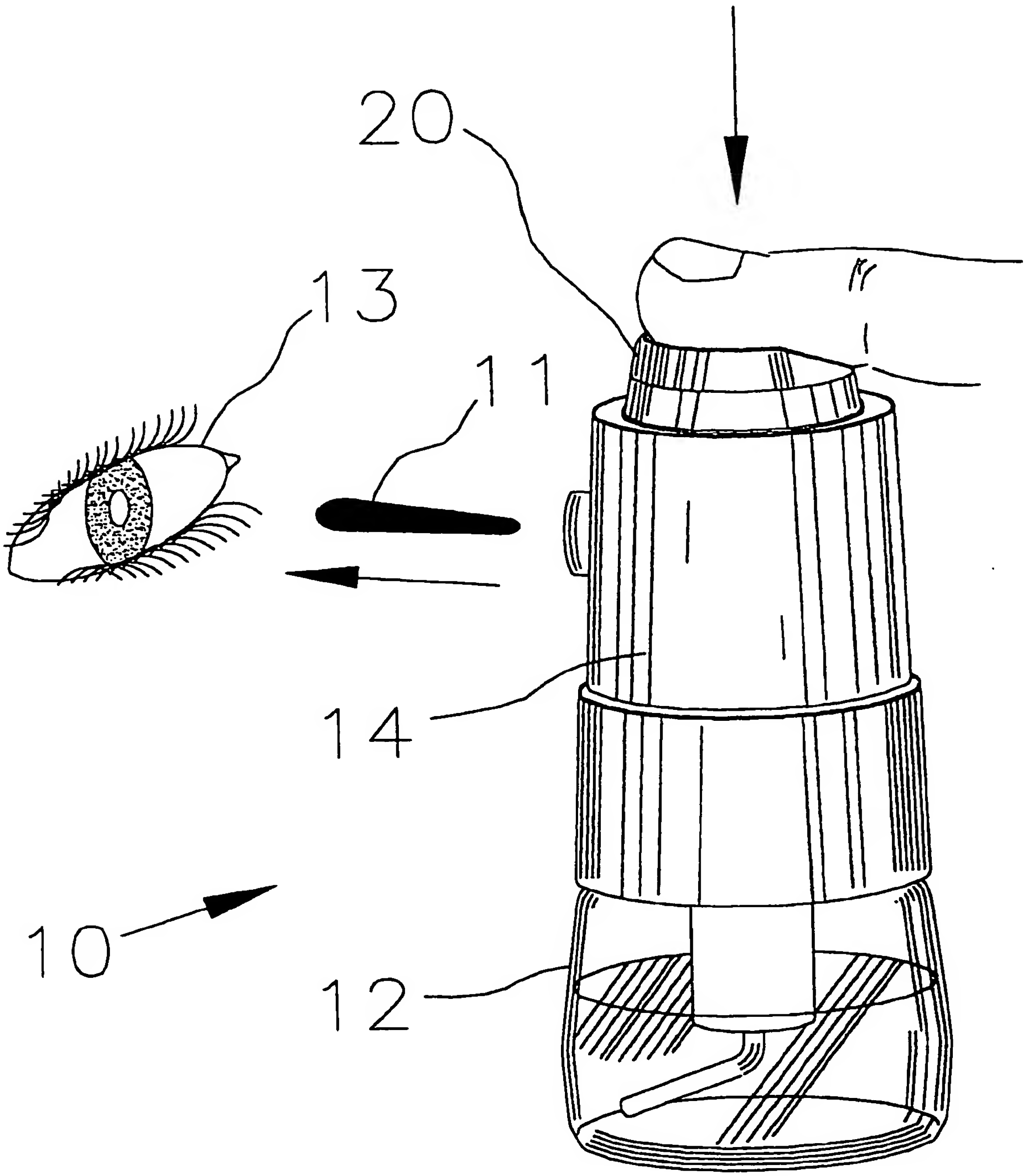

FIG.1

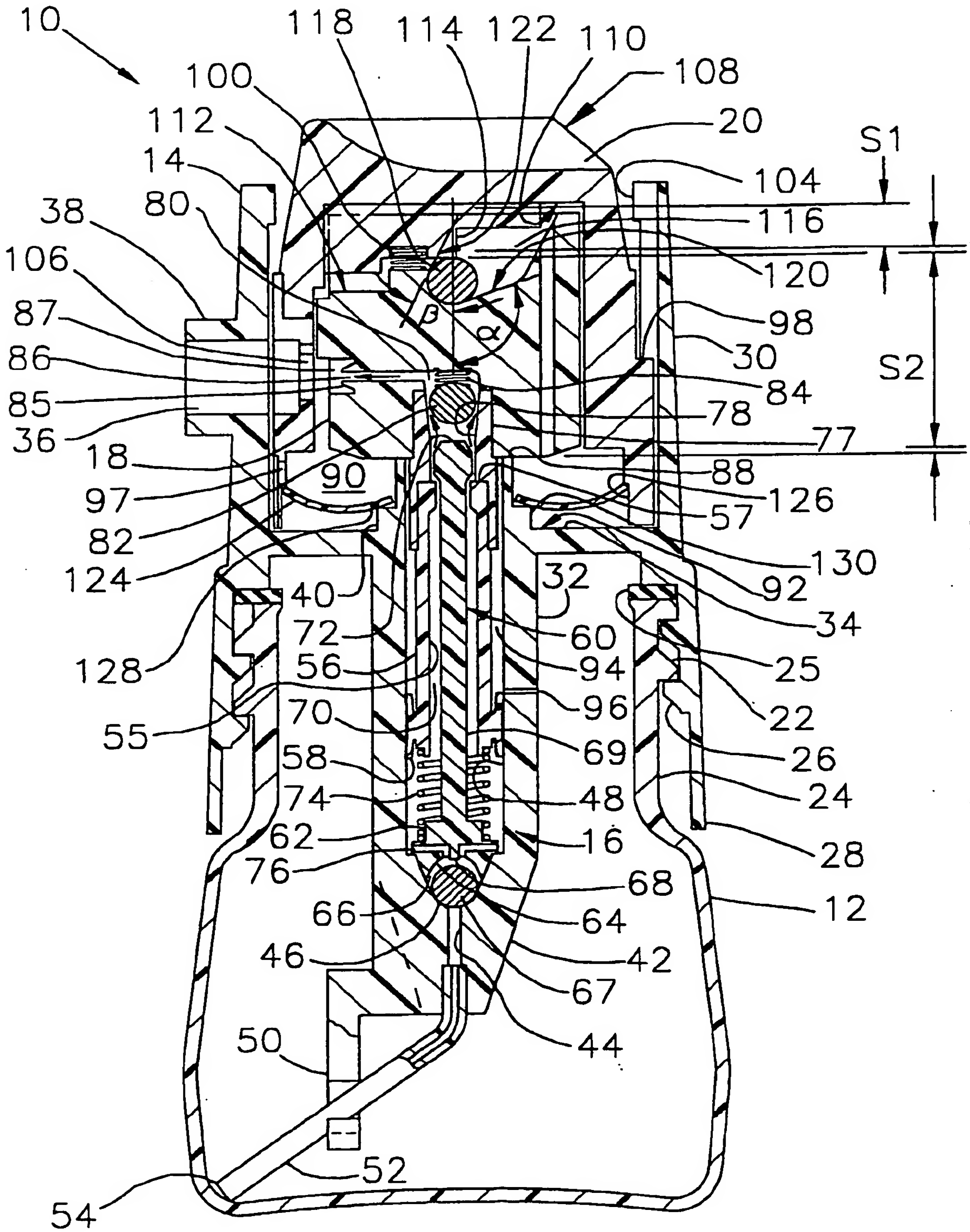
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FIG. 3

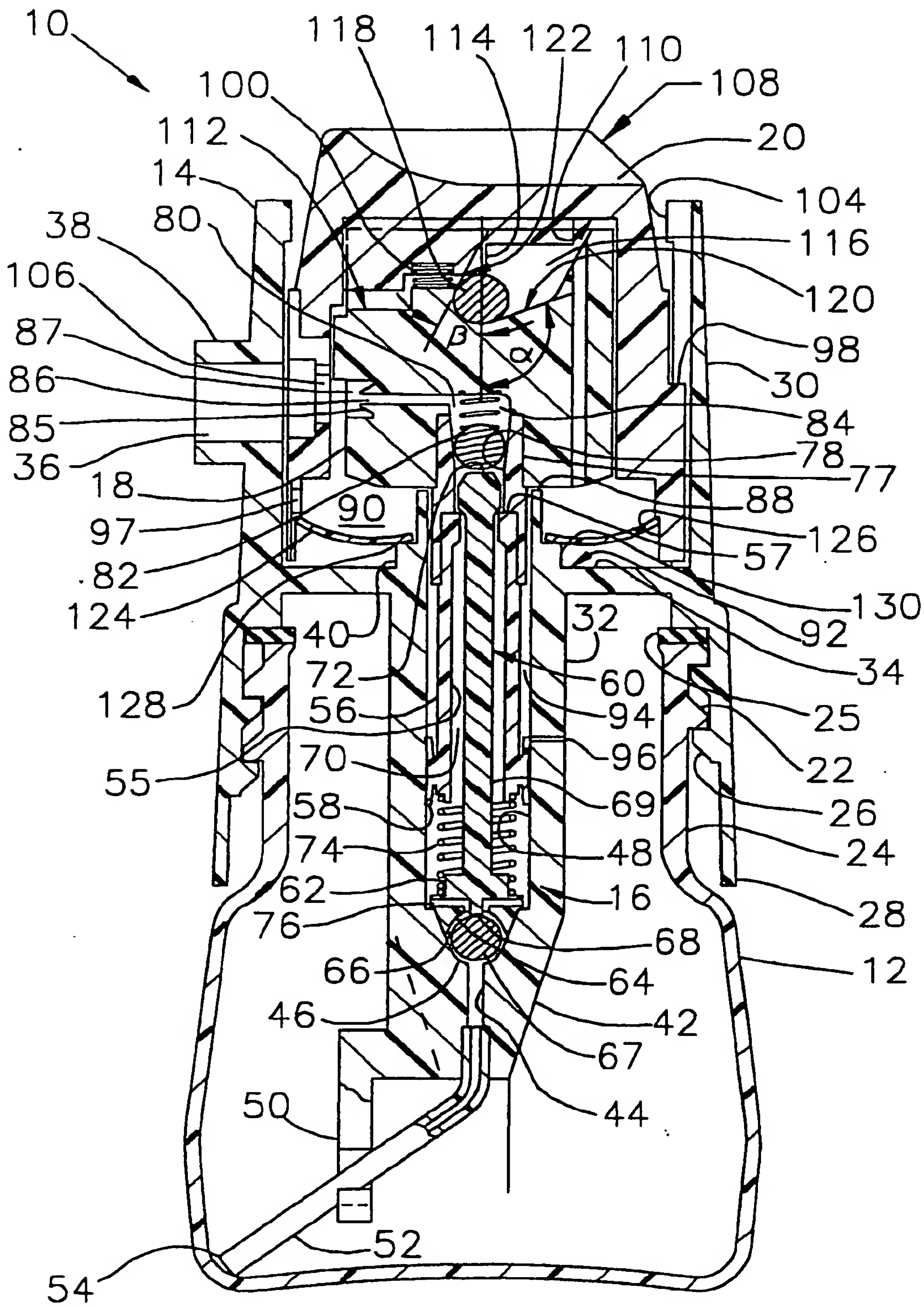
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FIG.5

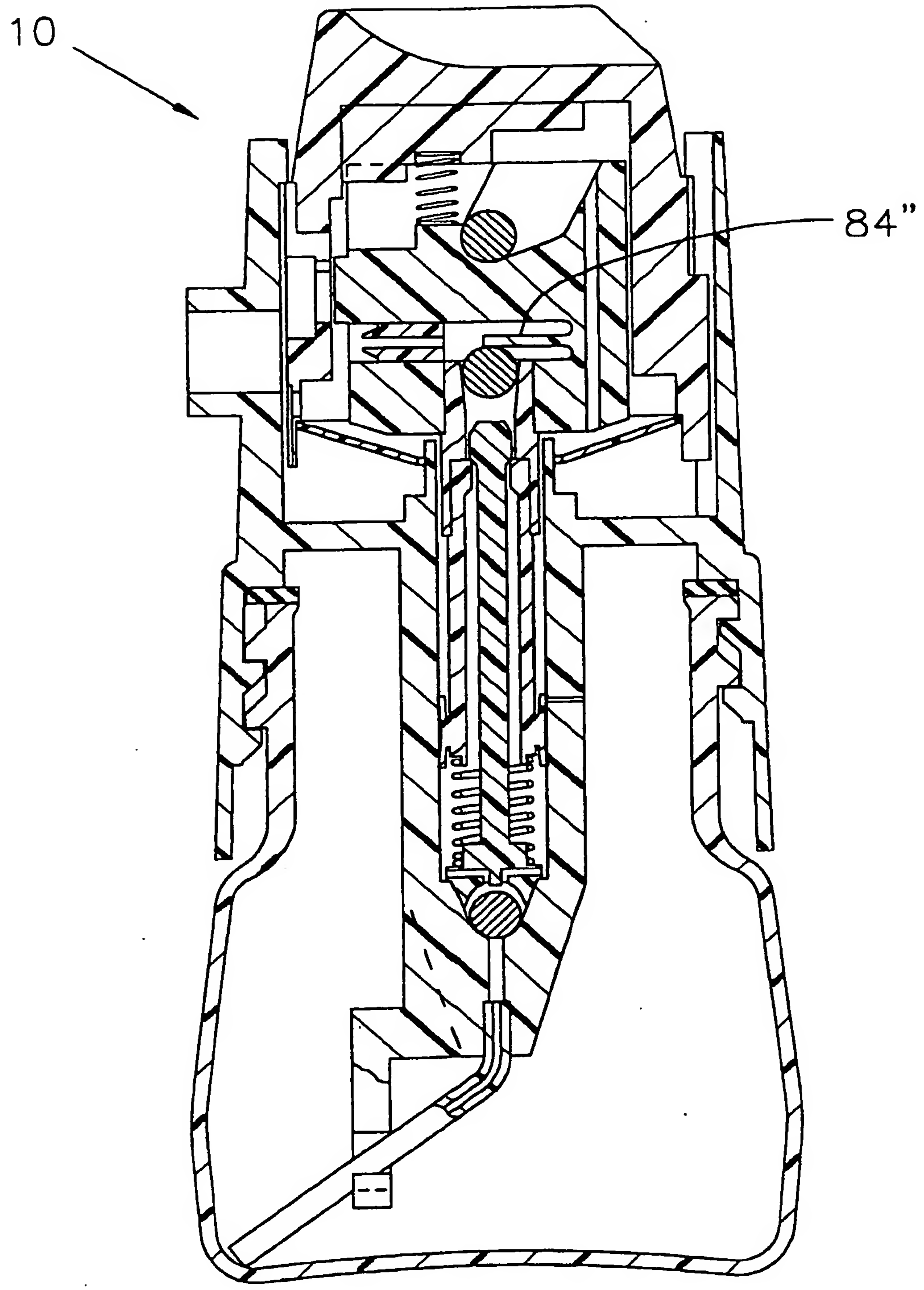

FIG.7

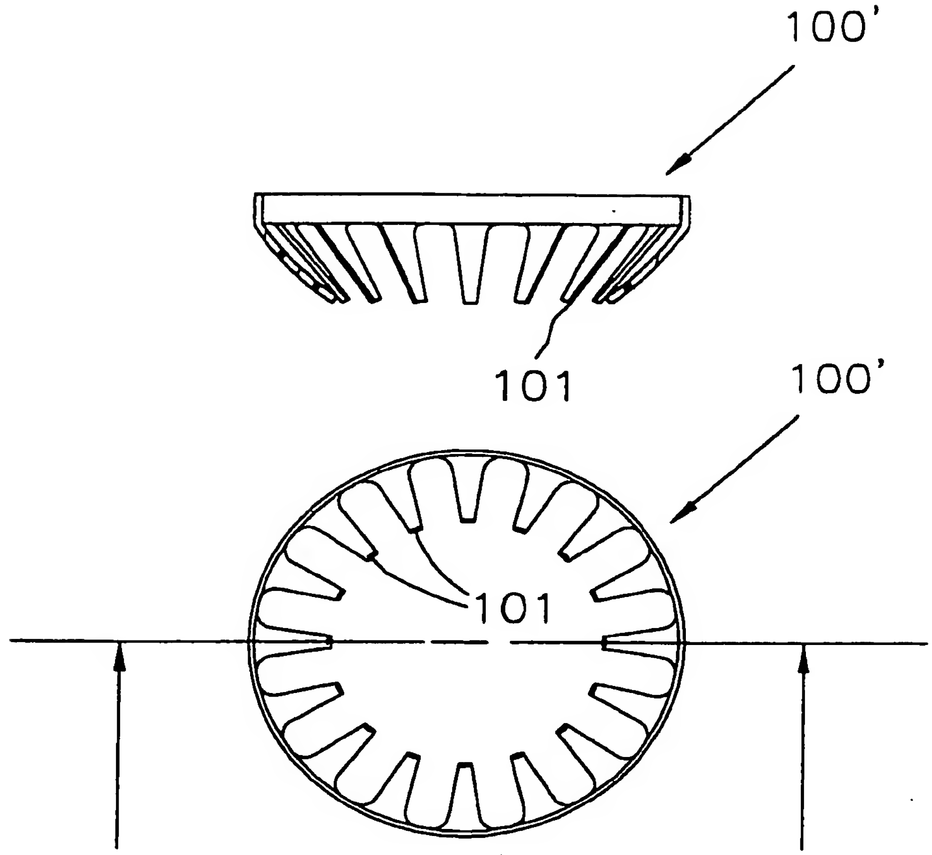

FIG.9

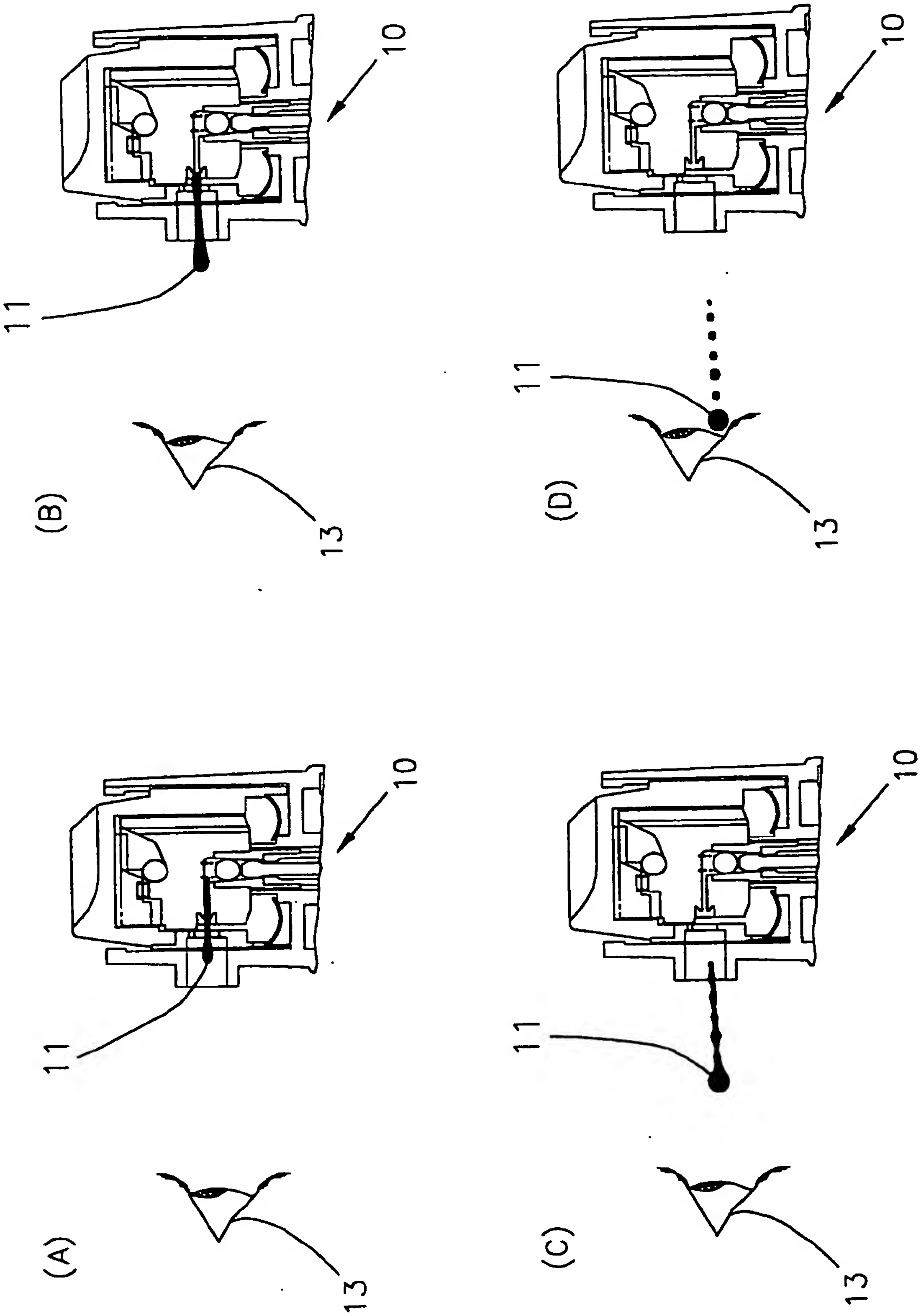

FIG. 11